

REMARKS

The subject application is directed to a method of improving the reproductive performance of sows which comprises feeding to the sows during at least two gestation periods and, optionally, during lactation, breeding and/or prebreeding L-carnitine or a salt thereof in combination with a trivalent chromium salt. It is acknowledged at the outset that both L-carnitine and certain salts of trivalent chromium, e.g., chromium picolinate, have been used individually to improve the reproductive performance of sows and that combinations have been tested during a single period of gestation for enhancing reproductive performances. This is amply shown in the references cited in the specification and Information Disclosure Statements filed herein. On the other hand, applicants have discovered that the combination of these two materials results in improved farrowing rate when administered during at least two parities. This was never tested, realized or contemplated by the prior art when it fed each of the components individually or in combination. The data set forth in the patent application show a synergistic response in this key reproductive area.

The claims stand rejected under 35 U.S.C 102(b) on the newly cited 1998 Samland et al. reference. The data presented in Samland et al. is a summary of previously reported data as is apparent from the titles of the Tables. Even Table 3, which makes reference to "Campbell et al., unpublished data" was in fact published before the Samland et al. article. Note in the Campbell article cited below and on page 3, ll. 17-19 of the specification.

More specifically, all the Tables of data in Samland et al. are substantially shown in the prior art already of record. Note the following:

Campbell, "The Effects of Chromium Picolinate on the Fertility and Fecundity of Sows under Commercial Conditions" dated 1996 cited on p. 3, ll. 17-19 of the specification.

Samland et al. **II**, "Ovulation and Fertilization Rate of Gilts Provided Additional L-Carnitine and Chromium Nicotinate" *Swine Day 1998*, published in November 1998, cited in the Information Disclosure Statement dated May 8, 2002.

Samland et al. **III**, "Effect of L-Carnitine and Chromium Nicotinate on the Ovulation and Fertilization Rate of Gilts" published in March 1999, cited on page 4, ll. 26-27 of the specification.

For the Examiner's convenience, the first and third of these articles are being submitted with the accompanying Information Disclosure Statement. To distinguish the reference cited by the Examiner from the above articles, the two Samland et al. articles have been designated above by the roman numerals II and III. Actually, the Samland III article is a later version of the Samland II article. For all intents and purposes, the articles are the same.

As set forth above, the independent claims pending in the application have been modified to clearly distinguish over the prior art. It is now specifically stated in these claims that the sows are fed a diet supplemented with L-carnitine or a salt thereof and a trivalent chromium salt during at least two gestation periods. As noted below, this technique is not described in the prior art, nor has the synergistic improvement in farrowing rate been shown.

Returning to Samland et al., it is emphasized that the data cited therein relating to L-carnitine was developed by Kansas State University investigators and that related to chromium by Campbell et al. No new data is presented. The article discusses certain theoretical mechanisms with regard to L-carnitine's and chromium's effect on sow reproductive performance. The authors postulate that these two compounds have different mechanisms of action (page 70, paragraph 2) and

speculate that these compounds “potentially could synergize to promote follicular growth and ovulation.” No test are described in which L-carnitine and chromium were administered during at least two periods of gestation. Furthermore, none of the test results in the article actually show the effect of using L-carnitine and chromium in combination to improve reproductive performance, let alone, second parity farrowing rates.

In the Summary of the article, the authors of Samland et al. direct their speculation to certain aspects of reproductive performance. Specifically, they mention that the use of the two compounds “*would be expected* to increase the litter size”, “*may affect* the number of follicles maturing and ovulating at estrus”, “*may be important* for stimulating ovulation rate in gilts”, and “*could synergize* to promote follicular growth and ovulation rates.” (Italics supplied) (page 70, last paragraph). Appropriately, the authors concludes:

“Therefore, ongoing research is [sic] evaluating the effects of additional L-carnitine and/or chromium nicotinate on ovulation and embryo implantation rate of gilts.”

This reference is merely a suggestion that it would be obvious to try using the two nutrients in question together: nothing more!

Not only are the comments made in Samland et al. speculative, but the data reviewed in the article would in no way suggest the synergistic effect discovered by the inventors with respect to second parity farrowing rate. In the case of R.G. Campbell’s 1996 work with chromium, *the supplemented feed was fed to the sows, whether a parity 1 or a parity 2 sow, for only one period, specifically, “from the day after mating through farrowing.”* This is clear from a reading of the first

experiment described in Campbell¹ (cited among the references on page 71 of Samland et al.) under the heading, **“Effects During Gestation in Young Sows.”** The parity numbers merely refer to the age of the sows.

In contrast, in the experiments reported in the instant application, gilts were fed the two nutrients during a first gestation and during their second gestation period (two parities). The data obtained, in other words, for the second parity were from the same sows from which the data were obtained for the first parity. *Each of the sows were fed during two separate and distinct periods.* Hence, the data reported by Campbell, R.G., 1996 cannot be compared to the data supporting the instant invention. In order to clarify this distinction, as noted above, the independent claims have been amended to note that the sows are fed the L-carnitine and the chromium *during at least two gestation periods.*

The data shown in Tables 7 and 8 of Samland et al. relates to the experiments on sows fed L-carnitine alone. Only Table 8 reports the effect on farrowing rate. Four diets were fed: (1) a control with no supplementation, (2) one supplemented with L-carnitine during the lactation period, (3) one supplemented with L-carnitine during the gestation period, and (4) one supplemented with L-carnitine during both the gestation and the lactation periods. The data obtained for percentage farrowing rate showed that the supplemented diets either did not substantially improve the percentage farrowing rate or actually decreased the percentage. And even more importantly, as in the case of the chromium supplementation, *each of the sows was fed the supplemented feed during*

¹ Table 1 of Campbell, R.G., 1996 contains the identical data which appears in Table 3 of Samland et al. It is not

only one parity. Accordingly, one skilled in the art would not expect L-carnitine, with or without chromium, to improve the percent farrowing rate aspect of reproductive performance. Hence, while arguably Samland et al. may have made it obvious to try the experiments, they did not substantiate any unexpected results. It is black letter law that patentability is not barred by prior art which merely makes an invention "obvious to try," where the inventors subsequently establish surprising and unexpected results. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); *In re Eli Lilly & Co.*, 902 F.2d 943, 945 (Fed. Cir. 1990) ("An 'obvious to try' situation exists when a general disclosure may pique the scientist's curiosity, such that a further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued.")

Samland III describes the "ongoing research" referred to in Samland et al. (see quote on page 8, *supra*) and shows that the authors of the Samland et al. reference sought to verify experimentally their earlier speculations. In the background of this latter publication (specifically in the two complete paragraphs on page 2), the speculations in the first reference are repeated almost verbatim, i.e., why it would appear to be useful to combine L-carnitine and chromium as a feed supplement for sows. Thereafter, the experiments are described which are to test empirically the validity of their earlier speculation. In these experiments, 100 gilts were fed a diet to evaluate the effect of adding 200 ppm of L-carnitine and 200 ppb of chromium nicotinate during one period of gestation. The data in Table 1 show that the number of eggs recovered for the combination

understood why Samland et al. in the caption to this Table refers to Campbell, et al as "unpublished data." On the other

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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